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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,302	10/16/2006	Jeremy Fairbank	UDL-121US	3386
23122	7590	01/30/2008	EXAMINER	
RATNERPRESTIA			PATTON, AMANDA K	
P O BOX 980			ART UNIT	PAPER NUMBER
VALLEY FORGE, PA 19482-0980			3762	
			MAIL DATE	DELIVERY MODE
			01/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,302

Applicant(s)

FAIRBANK ET AL.

Examiner

Amanda Patton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 15, 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 contains the phrase "so as to provide repeated localized external stimulation at one or more locations on the human body corresponding to the selected zone configurations so as to provide repeated localized external stimulation at one or selected activation zone configuration" in lines 3-6, This claim is unclear as the phrase "so as to provide repeated localized external stimulation at one" is repeated in a manner such that it is not clear to what it is referring.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 4, 18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Sieracki et al. (US Pat. 6,308,102, hereafter referred to as Sieracki).

Regarding **claims 1, and 4**, Sieracki teaches an apparatus for stimulation of the human body, comprising:

- an array of stimulator elements (e.g. array of electrodes 33) arranged to be operated in a plurality of stimulator activation zone configurations to effect localized stimulation of a human body corresponding to each of the activation zone configurations (e.g. the possible usable combination of the electrodes in electrode array 33 as stated in Col. 9, lines 37-54, used to adjust the neurostimulator settings for each patient); and
- a user interface device (e.g. patient interactive system 24, including display 30 and stylus 31) including a selectable array of independent input zones (e.g. the hand or foot of Figure 7A and B) to a respective stimulator element (e.g. spinal cord stimulation implant 29, wherein each stimulation electrode combination is considered a "stimulator element"; Col. 8, lines 15-40, Col. 9, lines 5-54) permitting the user to relate each input zone of the interface device to the respective stimulator element;

- wherein the apparatus is operable in a mode in which the patient is provided stimulation independent of their choice and then requested to indicate, on the display using the stylus, where they feel the stimulation (e.g. Col. 14 lines 5-25).

It is the examiner's position that the display showing the human body for indication on the display where the stimulation is felt is a selectable array of independent input zones (the selectable array being the parts of the body) which correspond to the activation zone array applied by the array of stimulator electrodes.

Regarding **claim 18**, Sieracki additionally teaches an apparatus wherein the stimulation intensity (e.g. amplitude threshold) of the stimulator elements can be varied (e.g. Col. 13, lines 49-53).

Regarding **claim 20**, Sieracki additionally teaches an apparatus including a control arrangement (e.g. computer 25) to control the interaction between the interface device (e.g. display 30) and the stimulator element array (e.g. electrode array 33, all as shown in Figure 3).

Regarding **claim 21 and 22**, Sieracki additionally teaches an apparatus that includes data transmitting means (e.g. IR transmission as shown in Figure 3) whereby results from the apparatus can be downloaded to a processor (e.g. personal computer 34) by a wireless connection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 10-11, 14-16, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann et al. (US Pat. 6,393,325, hereafter referred to as Mann) in view of Sieracki.

Regarding **claim 1 and 4**, Mann discloses the claimed invention including an apparatus for stimulation of the human body comprising:

- an array of stimulator elements (e.g. electrodes 24 as shown in Figure 5B) arranged to be operated in a plurality of stimulator activation zone configurations (e.g. electrodes 24, being used in a variety of electrode groups 45 as shown in Figures 6A and 6B and Col. 14, lines 45-50); and
- a user interface device permitting the user to relate independent interface zones of the interface device to activation zones of the array of stimulator elements (e.g. programming system 10 including display screen 16, directional control device 12, and keyboard 14 as shown in Figure 2 and Col. 11, lines 45-60);

Mann does not disclose a device operable in a mode in which the activation zone configuration of the array of stimulator elements is selected independently of the user and the user uses the interface device to identify the activation configuration as perceived by the user by selecting respective input zones on the user interface device. Sieracki teaches that it was known in the art to operate a device in a mode in which the activation zone configuration of the array of stimulator elements is selected independently of the user (e.g. Col. 14, lines 5-25 of Sieracki), and the user uses the interface device to identify the activation configuration as perceived by them by selecting respective input zones using the interface device (e.g. the user uses stylus 31 to indicate on display 30 the body which correspond to the activation zone array applied on the

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array of stimulator electrodes). It is the examiner's position that the display showing a human body for indication where the stimulation is felt is a selectable array of independent input zones (the selectable array being the parts of the body) that correspond to the activation zone array applied on the array of stimulator electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Mann to include the ability to operate in a mode wherein the activation zone configuration of the array of stimulator elements is selected independently of the user and the user uses the interface device to identify the activation configuration as perceived by the user by selecting respective input zones on the user interface device as taught by Sieracki, since such a modification would provide the system of Mann the ability to determining how different electrode arrays are perceived by the user for providing the predictable results of an easy way to optimize individual user stimulation.

Regarding **claim 2**, Mann additionally teaches an apparatus wherein the interface device (e.g. programming system 10) permits spatial correlation between the zones of the interface device (e.g. the zones shown in the pain drawing of Figure 12 shown on display 16) and the active zones of the activation zones (e.g. electrode groups 45) of the array of stimulator elements (e.g. electrodes 24) by providing both sets of data to computer 10 for analysis.

Regarding **claim 3**, Mann additionally teaches an apparatus wherein the interface device (e.g. programming system 10) includes an interface zone array (e.g. the pain drawing of Figure 12 shown on display 16) corresponding to the positional spacing of activation zones (e.g. electrode groups 45) of the array of stimulator elements (e.g. electrodes 24).

Regarding **claim 5**, Mann additionally teaches an apparatus operable in a second mode in which user input to the interface device determines the activation zone configuration of the array of stimulator elements (e.g. Col. 28, lines 50-60).

Regarding **claim 6**, Mann additionally teaches an interface device that includes an input zone array (e.g. the pain drawing of Figure 12 shown on display 16) corresponding spatially to the activation zone configuration of the array of stimulator elements.

Regarding **claim 10**, Mann additionally teaches an apparatus including a means for storing results data (e.g. memory circuit 54 as shown in Figure 2 and Col. 11, lines 55-62).

Regarding **claim 11**, Mann additionally teaches an apparatus wherein the array of stimulator elements (e.g. electrodes 24) are carried in a predetermined spatial relationship on a support member (e.g. electrode arrays 23, 23' and 23'' of Figures 6A, 6B, and 6C).

Regarding **claim 14**, Mann additionally teaches an apparatus wherein the support member (e.g. electrode array 23'') comprises an implant for insertion in the body (e.g. connected to pulse generator 20' as shown in Figure 6C, and Title).

Regarding **claim 15**, Mann additionally teaches an apparatus wherein the support member (e.g. electrode array 23'' of Figure 6C) includes space in between the electrodes, which can be considered barrier zones, in order to maximize attenuation beyond the locality of the stimulator elements.

Regarding **claim 16**, Mann additionally teaches an apparatus wherein the stimulator elements are arranged grid-wise in rows and columns (e.g. Col. 15 @ 10-20 and Figure 5B).

Regarding **claims 18 and 19**, Mann additionally teaches an apparatus wherein the stimulation intensity (e.g. pulse amplitude) and the activation duration (pulse width) of the stimulator elements can be varied (e.g. Col. 16, line 65 – Col. 17, line 5).

Regarding **claim 20**, Mann additionally teaches an apparatus including a control arrangement (e.g. stimulator processor 52) to control the interaction between the interface device (e.g. programming system 10) and the stimulator element array (e.g. electrode array 23, all as shown in Figure 2).

Regarding **claim 21 and 22**, Mann additionally teaches an apparatus that includes data transmitting means (e.g. coil 28 of the programming device and coil 62 of the implantable stimulator) whereby results from the apparatus can be downloaded to a processor (e.g. stimulator processor 52) by a wireless connection, wherein the processor is part of the programming system 10 and in one embodiment as shown in Figure 1A is a laptop.

Claims 17, 23, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sieracki in view of Brannon (US Pat. 6,193,678, hereafter referred to as Brannon).

Regarding **claim 17**, Sieracki discloses the claimed invention except stimulator elements that comprise vibrator devices. Brannon, however, teaches that it is known in the art to use vibratory units 18 (as shown in Figure 2 and Col. 3, lines 55-67) that act as stimulator elements. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Sieracki to include the vibratory units of Brannon, since such a modification would provide a the system with a vibratory electrode array for providing the predictable results of a device capable of provide more diverse treatment options.

Regarding **claims 23 and 27**, Sieracki discloses the claimed invention except the method step of stimulating of the surface of the body. Brannon teaches that it is known in the art to stimulate the surface of the body with an array of vibration units 18 (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sieracki to include the surface stimulator of Brannon, since such a modification would provide a method of applying an external electrode array to the body, for providing the predictable results of a way to stimulate portions of the body temporarily using a device that could be removed with relatively little effort.

Regarding **claim 26**, Sieracki additionally teaches an activation zone of the stimulator element array that provides stimulation independent of the user's choice and then requested to indicate, on the display using the stylus, where the stimulation is felt (Col. 14, lines 20-25).

Claims 12 and 13, are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann and Sieracki as applied to claim 1 above, and further in view of Brannon.

Regarding **claim 12**, Neither Mann or Sieracki disclose a support member comprising a garment to be worn by the user. Brannon teaches it is known in the art to have a stimulation system that includes a vest 12 containing a plurality of vibratory units 18 (Figure 2 and Col. 3, lines 55-67). It would have been obvious to one of ordinary skill at the time the invention was made to modify the system of Mann and Sieracki to include the vest and vibratory units of Brannon in order to provide an external electrode array for providing the predictable results of a temporary stimulatory device that can be removed with relatively little effort.

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Regarding **claim 13**, neither Mann, Sieracki, nor Brannon teach a garment comprising a corset. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system as taught by Mann, Sieracki, and Brannon with a corset, because Applicant has not disclosed that the corset provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the vest as taught by Brannon, because it provides an support for an external electrode array and the choice of a corset appears to be an arbitrary design consideration which fails to patentably distinguish over Mann, Sieracki, and Brannon. Therefore, it would have been an obvious matter of design choice to modify Mann, Sieracki, and Brannon to obtain the invention as specified in the claims.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sieracki and Brannon as applied to claim 23 above, and further in view of Mann.

Regarding **claim 24**, Sieracki and Brannon teach all of the limitations of the claim except an interface device that includes an array of interface zones corresponding spatially to stimulator element activation zones. Mann teaches that it is known in the art to use an interface device (e.g. programming system 10) that includes an array of interface zones (e.g. the zones shown in the pain drawing of Figure 12 shown on display 16) corresponding spatially to stimulator element activation zones (e.g. electrode groups 45 of Figure 5B). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Sieracki and Brannon with the interface device of Mann, since such a modification would provide the method with an array of interface zones corresponding spatially to stimulator

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element activation zones for providing the predictable results of a easier way to determine how the stimulator element activation zones correspond to the array on the interface zone.

Regarding **claim 25**, Sieracki and Brannon teach all of the limitations of the claim except a method in which the user input to a spatial input zone array of the interface device effects a corresponding spatial activation of the stimulator array. Mann teaches that it is known in the art to include the method step of using a user input (e.g. using joystick 12 or keyboard 14) to a spatial input zone array of the interface device (e.g. the zones shown in the pain drawing of Figure 12 shown on display 16) to effect a corresponding spatial activation of the stimulator array (e.g. electrode groups 45 of Figure 5B). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Sieracki and Brannon with the method step of Mann, since such a modification would provide the method with an way to effect the spatial activation of the stimulator array using the user input for providing the predictable results of allowing the user to indicate the best electrode array for their pain.

Response to Arguments

Applicant's arguments filed January 15, 2008 have been fully considered but they are not persuasive.

In response to Applicants assertion that Sieracki does not disclose, teach or suggest an apparatus including a user interface devices including a "selectable array of independent input zones, each input zone corresponding to a respective stimulator element, thereby permitting a user to relate each input zone of the interface device to the respective interface device to the

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respective stimulator element", Examiner disagrees. The display of Sieracki does permit the user to relate the independent input zones (e.g. the hand or the foot) to the respective stimulator element (e.g. the implanted electrodes) as each "stimulator element" stimulates and relates to an specific independent input zone. Examiner wishes to note that the claim does not require that the independent input zones be *non-overlapping* and relate to an *independent* "stimulator element", but rather simply to a respective stimulator element. Thus Sieracki discloses the claimed invention.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Woods et al. (US Pat. 6,609,032), Law et al. (US Pat. 5,938,690), and Daignault Jr. et al. (US Pat. 6,748,276) are three of many stimulator devices that teach the relation between independent input zones and respective stimulation devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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January 25, 2008


GEORGE R. EVANISKO
PRIMARY EXAMINER

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